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FDA TSE Advisory Committee Meeting
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Topic 4.
Suitability of Blood, Plasma and Tissue Donors Exposed to Various TSE Agents of Animals: Introduction, Charge and Questions

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Suitability of Blood, Plasma and Tissue Donors Exposed to Various TSE Agents of Animals: Introduction

- Scrapie of sheep and goats: human exposures have not been of concern (TSEAC June 3, 1999).
  - Long uneventful history of human exposures to infected animals and products
  - No convincing anecdotal (6 case series) or epidemiological (5 case-control studies) evidence of transmission to humans
  - CJD prevalences similar in countries with and without scrapie
  - Attempts to transmit scrapie (2 strains, several passage levels) to chimpanzees (ic+ip) failed

Suitability of Blood, Plasma and Tissue Donors Exposed to Various TSE Agents of Animals: Introduction (continued)

- Scrapie of sheep and goats: uncertainties (TSEAC June 3, 1999)
  - Multiple strains of scrapie agent have different biological properties
  - BSE agent may have originated as a strain of scrapie
  - Attempts to transmit scrapie to chimpanzees limited
  - Scrapie was transmitted to several species of monkey (no absolute species barrier for primates)
- TSEAC advice: Continue to avoid using sheep and goats with scrapie as sources of material to manufacture FDA-regulated injectable and implantable products.

Suitability of Blood, Plasma and Tissue Donors Exposed to Various TSE Agents of Animals: Introduction (continued)

- The FDA has received inquiries expressing concern about the potential transmissibility to humans of various TSEs of animals.
- Except for vCJD, no human TSE has been attributed to infection with an animal TSE agent.
- BSE agent, the presumed cause of vCJD, has never been found in US cattle.

Suitability of Blood, Plasma and Tissue Donors Exposed to Various TSE Agents of Animals: Introduction (continued)

As part of its commitment to ensure the safest possible supply of blood, blood components, plasma derivatives and tissue products, the FDA asks the TSEAC to consider whether exposure to any of the TSE agents known to infect animals in the USA or to the BSE agent, if accidentally introduced into the USA in an imported product, might pose sufficient risk as to compromise the suitability of blood, plasma or tissue donors.

Suitability of Blood, Plasma and Tissue Donors Exposed to Various TSE Agents of Animals: Program

The following sources of potential exposure to animal TSE agents within the USA will be discussed:

- Products derived from sheep and goats from BSE countries including imported sheep and progeny with undifferentiated TSE ("Vermont" sheep)
- Products derived from deer and elk with chronic wasting disease
- Ruminant-derived materials as components in dietary supplements

Suitability of Blood, Plasma and Tissue Donors Exposed to Various TSE Agents of Animals: Charge

- Please consider whether the agent of any animal TSE that occurs in the USA is likely to infect humans exposed to animals or to their products and whether the probability that blood, plasma or tissue donors have been infected is sufficient to warrant recommending their deferral.
- Please consider whether the BSE agent is likely to be accidentally imported into the USA in products or components of products and whether—without evidence that such importation has actually occurred—exposure of donors to any products poses sufficient risk to warrant recommending deferral.

Suitability of Blood, Plasma and Tissue Donors Exposed to Various TSE Agents of Animals: Questions

1. Should the FDA be sufficiently concerned about the suitability of any blood, plasma and tissue donors potentially exposed to TSE agents of animals, both agents known to infect animals in the USA and agents that might be accidentally imported, to consider recommending deferral?
2. If so, which animal TSE agents present in the USA or accidentally imported, what types of product and what intensity of exposure should be of concern?